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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 24

Application Number: 08/981,559
Filing Date: April 13, 1998
Appellant(s): WALLACH ET AL.

Roger L. Browdy
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed July 8, 2002 (Paper No. 21).

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Appellant states that "Appellant is aware of no other appeals ... which will directly affect ... or have a bearing on the Board's decision in the present appeal." However, at page 15 of the appeal brief Appellant states that the Board decision in Appeal No. 1999-0197 "is relevant to the present case and should be adopted."

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct insofar as claims 29 and 36 are pending. However, claims 29 and 36 are not under final rejection.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is incorrect.

The amendment after final rejection filed on February 26, 2001 (Paper No. 15) has been entered.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The rejection of claim 29 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly

point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

(7) Grouping of Claims

The rejection of claims 29 and 36 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

A substantially correct copy of appealed claims 29 and 36 appears on page 1 of the Appendix to the appellant's brief. The minor errors are as follows: In claim 29, line 4, the phrase "screening each molecule" should be "testing each molecule." In claim 29, line 10, the phrase "cause modulation" should be "cause said modulation."

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10)(a) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 29, 36 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are drawn to or encompasses a method of screening for compounds that bind the intracellular domain of 26 kDa TNF and/or modulate the phosphorylation thereof. The specification teaches phosphorylation of the serine residues of the intracellular domain of 26 kDa TNF. However, the biological significance of this phosphorylation is unknown. In the absence of a knowledge of the biological significance of the phosphorylation process there is no apparent

specific and substantial asserted utility or a well established utility for either the screening process or production of the compounds identified by the screening process. Further experimentation is necessary to attribute a utility to the claimed screening process. Evidence warranting further study is not equivalent to evidence showing the type of utility required by 35 U.S.C. 101. See Brenner v. Manson, 383 U.S. 519, 535□36, 148 USPQ 689, 696 (1966) (noting that in context of the utility requirement "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.").

Claims 29, 36 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

(11)(a) Response to Argument

Appellant argues that it is incorrect that the biological significance of this phosphorylation is unknown, citing page 6, lines 3-10, of the specification. Appellants' arguments have been fully considered but they are not persuasive. The specification discloses at page 6, lines 3-10, that the "findings and their related functional significance represent the first disclosure of a control possibility." The specification at the paragraph bridging pages 5-6 also discloses that the sequence conservation of the intracellular domain of TNF indicates that this domain and its phosphorylation play important roles in TNF function. One possibility is that this domain take part in the regulation of proteolytic processing. Another possibility is that this domain may affect TNF function as a ligand. Yet another possibility is that this intracellular domain interacts with other intracellular molecules. The specification at page 6, full paragraph

1, discloses that the phosphorylation of the intracellular domain of TNF may be involved in the regulation of expression or proteolytic processing of cell-surface TNF, in the modulation of TNF bioactivity, or in the intracellular processes mediated by the cell surface TNF molecules. None of these are specific because the specification does not indicate the specific way in which TNF processing, activity, or interaction are modulated by phosphorylation. Further, the biological significance of the phosphorylation of the intracellular domain of TNF is unknown. Thus the asserted utility in screening for factors that modulate the phosphorylation of the intracellular domain of TNF is not substantial, because further research would have to be conducted to determine which, if any, of TNF activity or processing are modulated and how they are modulated. The specification lacks specific and substantial disclosure of a specific and substantial functional consequence of this phosphorylation. In the absence of a particular disclosed relationship between the phosphorylation of the intracellular domain of TNF and a particular functional consequence, any information obtained from the claimed method would only serve as the basis for further research on the observation itself. The claimed method itself and the proposed uses of the claimed method are simply starting points for further research and investigation into potential practical uses of the claimed methods. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." Brenner v. Manson, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101 because any potential utility of the claimed method is not yet known. Given these considerations, the claimed method has no "well-established" use. The artisan is required to perform further experimentation to determine to what "use" any information regarding the results of the screening could be put.

One must know the biological significance of such phosphorylation in order to determine what "use" the claimed method could be put. Without knowledge of this biological significance the results of the claimed method are useless because one would not know what significance could be attributed to any modulation in such phosphorylation.

Appellant argues that phosphorylation of the cell-bound TNF constitutes part of the normal way of TNF modulation, citing page 12, lines 17-20, of the specification. Appellants' arguments have been fully considered but they are not persuasive. An assertion that phosphorylation of the cell-bound TNF constitutes part of the normal way of TNF modulation is not specific because it does not indicate a modulation of a particular activity. Such an assertion is also not substantial because it does not indicate a particular way in which a particular activity is modulated.

Appellant argues that phosphorylation plays an important role in TNF function, citing page 13, lines 5-6, of the specification. Appellants' arguments have been fully considered but they are not persuasive. An assertion that phosphorylation plays an important role in TNF function is not specific and substantial because it does not indicate a particular role in a particular TNF function.

Appellant argues that the finding of phosphorylation of the intracellular domain of TNF provides a basis for pinpointing agents that can modulate the shedding of TNF or modulate the activity of TNF, citing page 14, lines 1-7, of the specification. Appellants' arguments have been fully considered but they are not persuasive. Based on the specification's disclosure at page 6, lines 3-10, (the "findings and their related functional significance represent the first disclosure of a control possibility"), at the paragraph bridging pages 5-6 (the sequence conservation of the

intracellular domain of TNF indicates that this domain and its phosphorylation play important roles in TNF function. One possibility is that this domain take part in the regulation of proteolytic processing. Another possibility is that this domain may affect TNF function as a ligand. Yet another possibility is that this intracellular domain interacts with other intracellular molecules.), and the disclosure at page 6, full paragraph 1, (the phosphorylation of the intracellular domain of TNF may be involved in the regulation of expression or proteolytic processing of cell-surface TNF, in the modulation of TNF bioactivity, or in the intracellular processes mediated by the cell surface TNF molecules), the disclosure at page 14, lines 1-7, of the specification is describing a "wish to know" type of utility, which is not a specific and substantial utility.

Appellant argues that compounds that modulate phosphorylation can be further tested for their biological activity, citing page 38 of the specification, and that this further screening in vivo for biological activity is a specific and substantial utility. Appellants' arguments have been fully considered but they are not persuasive. Firstly, page 38 discloses further testing of compounds that bind the intracellular domain of TNF and says nothing regarding the further screening of compounds that modulate phosphorylation. Secondly, this further testing of any compound that modulates phosphorylation would only serve as the basis for further research on the result of the claimed method itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." Brenner, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101.

Appellant argues that the screening process is useful to find molecules that cause modulation of phosphorylation in view of the further assertion that such modulation would be expected to modulate the biological activity of TNF. Appellants' arguments have been fully considered but they are not persuasive. The statement that such modulation would be expected to modulate the biological activity of TNF is not specific because it does not indicate a modulation of a particular activity. Such a statement is also not substantial because it does not indicate a particular way in which a particular activity is modulated.

Appellant argues that compounds that modulate TNF may be used for the treatment of specific conditions, citing page 2, lines 8-29, of the specification. Appellants' arguments have been fully considered but they are not persuasive. Although compounds that modulate TNF activity may be used for the treatment of specific conditions, the biological significance of the phosphorylation of the intracellular domain of TNF is unknown. Consequently, it is unknown whether any such compounds found through the claimed method could be used for treatment of specific conditions.

Appellant argues that there is a specific assertion that that compounds found will have a specific and substantial use in treating specific conditions. The biological significance of the phosphorylation of the intracellular domain of TNF is unknown. The specification lacks specific and substantial disclosure of a specific and substantial functional consequence of this phosphorylation. Thus the asserted utility in screening for factors that modulate the phosphorylation of the intracellular domain of TNF is not substantial, because further research would have to be conducted to determine which, if any, of TNF activity or processing are modulated and how they are modulated. The claimed method itself and the proposed uses of the

claimed method are simply starting points for further research and investigation into potential practical uses of the claimed methods. In the absence of a particular disclosed relationship between the phosphorylation of the intracellular domain of TNF and a particular functional consequence, any information obtained from the claimed method would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." Brenner v. Manson, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101. Because any potential utility of the claimed method is not yet known, any utility of the compounds found using the claimed screening process are not currently available in practical form.

Appellant argues that the successful screening test of the presently claimed invention will marshal resources and direct the expenditure of effort to further in vivo testing of the most potent compounds, which has been held to be a specific and substantial utility. Appellants' arguments have been fully considered but they are not persuasive. The biological significance of the phosphorylation of the intracellular domain of TNF is unknown. The specification lacks specific and substantial disclosure of a specific and substantial functional consequence of this phosphorylation. Thus the asserted utility in screening for factors that modulate the phosphorylation of the intracellular domain of TNF is not substantial, because further research would have to be conducted to determine which, if any, of TNF activity or processing are modulated and how they are modulated. The claimed method itself and the proposed uses of the claimed method are simply starting points for further research and investigation into potential practical uses of the claimed methods. In the absence of a particular disclosed relationship

between the phosphorylation of the intracellular domain of TNF and a particular functional consequence, any information obtained from the claimed method would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." Brenner v. Manson, 148 USPQ at 696. Because any potential utility of the claimed method is not yet known, any marshaling of resources and directing the expenditure of effort to further in vivo testing of the most potent compounds would only serve as the basis for further research on the observation itself. Because the claimed method itself and the proposed uses of the claimed method are simply starting points for further research and investigation into potential practical uses of the claimed methods any marshaling of resources and directing the expenditure of effort to further in vivo testing of the most potent compounds cannot be held to be a specific and substantial utility.

Appellant argues that the rejection under 35 U.S.C. § 112, first paragraph is based on the same reasons as the rejection under 35 U.S.C. 101 and should therefore be overturned. As Applicants recognize, a rejection under § 112, first paragraph, may be maintained on the same basis as a lack of utility rejection under § 101. A deficiency under 35 U.S.C. 101 also creates a deficiency under 35 U.S.C. 112, first paragraph. If the application fails as a matter of fact to satisfy 35 U.S.C. § 101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. § 112. Obviously, if a claimed invention does not have utility, the specification cannot enable one to use it. As such, a rejection properly imposed under 35 U.S.C. 101 should be accompanied with a rejection under 35 U.S.C. 112, first paragraph. The 35 U.S.C. 112, first paragraph, rejection set out a separate rejection

that incorporates by reference the factual basis and conclusions set forth in the 35 U.S.C. 101 rejection. A 35 U.S.C. 112, first paragraph, rejection should be imposed or maintained when an appropriate basis exists for imposing a rejection under 35 U.S.C. 101.

(10)(b) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 29 and 36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are directed to "producing" a molecule. However, the specification does not describe the production of any and all molecules with the desired characteristics. At best it might be obvious to the skilled artisan that it would be desirable to employ the materials and methods disclosed in attempt to produce such molecules. However, the written description does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed. One shows that one is 'in possession' of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious.

(11)(b) Response to Argument

Appellant argues that the claims do not require that any molecule which causes modulation of the phosphorylation be actually identified, and that in this regard the preset case is similar to U.S. application serial no. 08054970, and that the same logic in the Board decision obviously applies to whether applicant was in possession of the method. Appellants' arguments

have been fully considered but they are not persuasive. Appellant is reminded that Vas-Cath Inc. v. Mahurkar , 19 USPQ2d 1111makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115). Accordingly, the same logic in the Board decision would not necessarily apply to whether applicant was in possession of the claimed method. It is true that a molecule that is not identified by the process need not be produced. However, in the present case the claims require producing in substantially isolated and purified form any said molecule which is determined to cause said modulation. The specification does not describe the production of any and all molecules with the desired characteristics.

Appellant argues that if no molecule is determined to cause the modulation then nothing need be produced. Appellants' arguments have been fully considered but they are not persuasive. It is true that a molecule that is not identified by the process need not be produced. However, in the present case the claims require producing in substantially isolated and purified form any said molecule which is determined to cause said modulation. The specification does not describe the production of any and all molecules with the desired characteristics.

Appellant argues that if a molecule is identified by the screening step then producing it is a trivial matter, citing page 27, lines 5-11. Appellants' arguments have been fully considered but they are not persuasive. Page 27, lines 5-11, of the present specification apparently refers to the screening of molecules that bind the intracellular domain of TNF, whereas the present claims are directed to the screening of molecules that modulate the phosphorylation of the intracellular domain of TNF. As provided for in the present specification, molecules that modulate the phosphorylation of the intracellular domain of TNF are not limited to molecules that bind the

intracellular domain of TNF and include molecules that interact with one or more other intracellular effector proteins which interact with the intracellular domain of TNF or with one or more kinase enzymes involved in the phosphorylation of the intracellular domain of TNF. See the present specification at page 6, full paragraph 3, and paragraph bridging pages 6-7. Accordingly, the claims are not limited to screening for molecules that bind the intracellular domain of TNF. Page 27, lines 5-11, of the present specification also provides for new proteins and peptides of the invention once isolated, identified, and characterized to be produced by any standard recombinant DNA technique. However, the present claims are not limited to the screening of peptides and proteins and are not limited to the production of peptides and proteins by any standard recombinant DNA technique. The present claims encompass the screening and production of any all molecules that modulate the phosphorylation of the intracellular domain of TNF. As provided for in the present specification, molecules that modulate the phosphorylation of the intracellular domain of TNF can be naturally-derived proteins, peptides, analogs and derivatives thereof, and organic compounds. Any standard recombinant DNA technique does not describe the production of any or all organic compounds capable of such modulation. Whether or not the production of any or all organic compounds capable of such modulation is trivial is dependent upon the compound.

Appellant argues that Applicant was in possession of the concept of producing a pure compound which has been identified, using synthesis processes already established in the art. Applicant's arguments have been fully considered but they are not persuasive. Production in substantially isolated and purified form any molecule which is determined to cause modulation of the phosphorylation of the intracellular domain of TNF is necessary to practice the claimed

method. This production is only described in terms of a general concept and the specification does not describe the production of any and all molecules with the desired characteristics. Specific, not general, i.e., "producing", guidance is needed to practice the invention. The concept of producing the desired molecules is no more than a wish for obtaining the required producing process. The concept of producing the desired molecules contains no information by which the skilled artisan would understand that Appellant possessed the claimed invention. Without a specific producing process it is impossible to practice the claimed method. The present specification describes how to screen compounds to determine whether they work, but it does not describe the production of any and all molecules with the desired characteristics.

Appellant argues that Applicant is not claiming molecules, that Applicant is claiming a screen, and that Applicant is in possession of the concept of screening. Appellants' arguments have been fully considered but they are not persuasive. Production in substantially isolated and purified form any molecule which is determined to cause modulation of the phosphorylation of the intracellular domain of TNF is necessary to practice the claimed method. This production is only described in terms of a general concept and the specification does not describe the production of any and all molecules with the desired characteristics. Specific, not general, i.e., "producing", guidance is needed to practice the invention. The concept of producing the desired molecules is no more than a wish for obtaining the required producing process.

Appellant argues that because the claim does not require that any such molecules be found it is not necessary to identify any such molecule, but that once identified the molecule can be produced, and therefore Applicant was in possession of the idea of producing any molecule found. Appellants' arguments have been fully considered but they are not persuasive.

Production in substantially isolated and purified form any molecule which is determined to cause modulation of the phosphorylation of the intracellular domain of TNF is necessary to practice the claimed method. This production is only described in terms of a general concept and the specification does not describe the production of any and all molecules with the desired characteristics. Specific, not general, i.e., "producing", guidance is needed to practice the invention. The concept of producing the desired molecules is no more than a wish for obtaining the required producing process.

Appellant argues that there is nothing in 35 U.S.C. § 112, first paragraph which requires that such molecules be identified before one can be in possession of a screening process. Production in substantially isolated and purified form any molecule which is determined to cause modulation of the phosphorylation of the intracellular domain of TNF is necessary to practice the claimed method. This production is only described in terms of a general concept and the specification does not describe the production of any and all molecules with the desired characteristics. Specific, not general, i.e., "producing", guidance is needed to practice the invention. The concept of producing the desired molecules is no more than a wish for obtaining the required producing process.

(10)(c) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 29, 36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

invention. The claims are directed to "producing" a molecule. However, the specification does not describe the production of any and all molecules with the desired characteristics. In the absence of this information the skilled artisan would have to resort to a substantial amount of unduly extensive, random, trial and error experimentation in the form of random analysis of any and all compositions and/or compounds and through trial and error experimentation is left to determine how to isolate and produce them. In view of the breadth of the claims, the limited amount of direction and working examples provided by the inventor, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

(11)(c) Response to Argument

Appellant refers to the Board decision in U.S. application serial no. 08/054,970 and Appellant's reconstruction of the passage at page 8 of the decision is acknowledged. Appellants' arguments have been fully considered but they are not persuasive. It is not a question of whether the screening step would or would not determine if a molecule causes modulation of the phosphorylation. It is a question of whether the specification has enabled the production in substantially isolated and purified form any such molecule which is determined to cause such modulation.

Appellant argues that the production in substantially isolated and purified form any such molecule which is determined to cause such modulation would not require undue experimentation because the specification teaches how to run a screen, citing example 6 of the present specification. Appellants' arguments have been fully considered but they are not

persuasive. Example 6 of the present specification essentially calls for the use of trial and error experimentation to attempt to find a compound that may in some way be related to phosphorylation of the intracellular domain of TNF. Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Tossing out the mere germ of an idea does not constitute an enabling disclosure. Reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. However, the present specification does not describe a repeatable process of producing any and all molecules with the desired characteristics. When there is no disclosure of the conditions under which the required producing process can be carried out, undue experimentation is required. There is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. The specification does not explain how the skilled artisan can produce in substantially isolated purified form any or all molecules that modulate phosphorylation of the intracellular domain of TNF.

Appellant argues that running a screen is not random trial and error. Appellants' arguments have been fully considered but they are not persuasive. The mere running of a screen is nothing but random, trial and error experimentation.

Appellant argues that the present claims are directed to a screening process and not to the molecules found. Appellants' arguments have been fully considered but they are not persuasive. The claims require producing in substantially isolated and purified form any said molecule which is determined to cause said modulation. It is this "producing" process that is the subject of this rejection.

Appellant argues that "a substantial amount of unduly extensive, random, trial and error experimentation in the form of random analysis of any and all compositions and/or compounds and through trial and error experimentation" is merely conclusionary, without analytic back-up, and is no substitute for a fact-based explanation why undue experimentation is required. Appellants' arguments have been fully considered but they are not persuasive. The specification does not describe the production of any and all molecules with the desired characteristics. In the absence of this information the skilled artisan would have to resort to a substantial amount of unduly extensive, random, trial and error experimentation in the form of random analysis of any and all compositions and/or compounds and through trial and error experimentation is left to determine how to isolate and produce them. The rejection is based on no disclosure of the conditions under which the required producing process can be carried out. When there is no disclosure of the conditions under which the required producing process can be carried out, undue experimentation is required. There is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. The specification does not explain how the skilled artisan can produce in substantially isolated purified form any or all molecules that modulate phosphorylation of the intracellular domain of TNF.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

David S Romeo
Primary Examiner
Art Unit 1647

DSR
May 30, 2003

Conferees

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